ENVIRONMENTAL PROTECTION AGENCY

[OPTS-47002J; FRL 3847-2]

RIN 2070-AC31

TSCA Section 4(a)(1)(B) Proposed Statement of Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Statement of Policy.

SUMMARY: EPA is proposing standards and criteria it intends to use in interpreting its legal authority to make findings under the Toxic Substances Control Act (TSCA) section 4(a)(1)(B)(i) for determining substantial production, release to the environment in substantial quantities, and substantial or significant human exposure. This policy is not intended to address how EPA establishes priorities for testing or whether any individual chemical should be tested. Further, EPA does not intend to require testing of every chemical that meets the criteria under TSCA section 4(a)(1)(B)(i) as articulated in this notice because EPA must also find under TSCA section 4(a)(1)(B)(ii) and (iii) that data are inadequate to determine or predict the effects of the chemical and that testing of such chemical is necessary. This notice is not intended to address the policy issues related to how EPA identifies candidates for testing. For the reasons articulated in this notice, EPA is proposing that in cases where the actual numbers for production, release, or exposure are above certain quantitative numerical thresholds, these numbers are per se substantial. Furthermore, EPA proposes that such findings are also appropriate in situations where the quantitative numerical thresholds are not met, if "additional factors" exist. EPA will continue to develop and refine the criteria as its experience with chemicals considered for testing evolves, particularly with regard to the findings of significant human exposure, for which EPA is not proposing a minimum cut-off in this notice. If EPA needs to provide further rationale for its findings beyond the explanation presented in this proposal, EPA will articulate the criteria used in making such findings in the proposal for that individual test rule. This notice also addresses the application of the proposed criteria to EPA's existing cumene test rule (July 27, 1988, 53 FR 28195).

DATES: Submit written comments on or before September 13, 1991.

ADDRESSES: Written comments, in duplicate, identified by the docket number (OPTS-47002J) for the proposed TSCA section 4(a)(1)(B) policy definitions should be submitted to: TSCA Public Docket Office (TS-793), Office Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M St., SW., Washington, DC 20460. A public version of the administrative record supporting this action is available for inspection at the above address from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays.

Information submitted in any comment on this notice may be claimed as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be disclosed publicly by EPA by placing it in the public record without prior notice to the submitter.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is proposing to establish quantitative criteria (numerical thresholds) and other factors for evaluating "substantial production," "substantial" and "significant" exposure, and "substantial" release findings as set forth in test rules developed under TSCA section 4(a)(1)(B). In *Chemical Manufacturers Association et al.*, v. *Environmental Protection Agency*, 899 F.2d. 344, (5th Cir. 1990), the Fifth Circuit Court of Appeals (the "Court") remanded to EPA the rule requiring cumene testing and required EPA to articulate criteria for the findings EPA made in the cumene test rule (53 FR 28195). EPA has decided to use this opportunity to propose criteria for making all findings under section 4(a)(1)(B)(i) of TSCA.

I. Introduction

Under section 4(a)(1)(B) of TSCA, EPA must require testing of a chemical substance or mixture (chemical) to develop health effects, environmental effects, or chemical fate data, or other data relevant to determining risk, if it finds that:

(1) The chemical substance or mixture is or will be produced in substantial quantities, and (a) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (b) there is or may be significant or substantial human exposure to such substance or mixture,

(2) There are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted, and

(3) Testing of such substance or mixture with respect to such effects is necessary to develop such data.

These are known as "release or exposure-based" findings as opposed to the "risk-based" findings of TSCA section 4(a)(1)(A).

On April 12, 1990, the Court remanded to EPA the TSCA section 4 test rule for cumene in response to a challenge to the rule by the Chemical Manufacturers Association (CMA). The Court generally upheld EPA's factual findings in the rule as being supported by substantial evidence but instructed EPA to "*** articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from the facilities in question to be 'substantial' and potentially resulting human exposure to be 'substantial'." EPA decided to use the opportunity to explain its criteria for making all legal findings under section 4(a)(1)(B)(i) of TSCA. This notice is not intended to address EPA's policy decisions for selecting chemicals as potential candidates for testing. After consideration of public comments, EPA will publish a final notice on this policy.

TSCA provides EPA with little guidance on what criteria and standards should be used in making section 4(a)(1)(B) findings. The statute does not define the terms "significant" or "substantial." It is useful, however, to understand EPA's legal authority in TSCA section 4 in the context of the entire statute. The general purposes of TSCA are set forth in TSCA section 2(b):

> (b) Policy.—It is the policy of the United States that—
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> (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
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> (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
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> (3) authority over chemical substances and mixtures should be exercised in such a

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manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment (15 U.S.C. 2601(b)(1)).

As explained in section 2 of TSCA, testing is only a first step. Once test data are obtained, EPA can then consider whether any regulatory restrictions on the manufacturing, processing, distribution in commerce, use, and disposal of the chemical are necessary. If EPA decides that the chemical presents an unreasonable risk of injury, EPA may then initiate rulemaking under section 6 of TSCA. Since testing is only a first step in protecting the public from unreasonable risk of injury to health and the environment, Congress gave EPA broad authority to require testing of chemicals not only when there is some preliminary concern about the chemical (TSCA section 4(a)(1)(A)), but also in the case of chemicals with large production (and release or exposure), even in the absence of any information that the chemical may be hazardous to human health or the environment. This makes sense because in the case of "large" production volume chemicals, it is most likely that these chemicals may have either the release or human exposure scenarios that EPA may wish to restrict based on the results of testing.

The legislative history of TSCA provides some guidance on criteria to be used in making section 4(a)(1)(B) findings: "The conditions specified in (TSCA) section 4(a)(1)(B) reflect the Committee's recognition that there are certain situations in which testing is desirable even though there is an absence of information indicating that the substance or mixture may be harmful" (H. Conf. Rept. 1341, 94th Cong., 2d sess. (1976), at 18 reprinted in, A Legislative History of the Toxic Substances Control Act (Comm. Print 1976) ("Legislative History") at 425) and "* * * there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture per se may be hazardous" (H. Conf. Rept. 1679, 94th Cong., 2d sess. (1976), at 61 reprinted in, Legislative History at 674). The legislative history also indicates that "* * * the Administrator is not limited to consideration of sheer volume of production or exposure at a specific point in time. The duration of the exposure, the level of or intensity of exposure at various periods of time, the number of people exposed, or the extent of environmental exposure are among the considerations which may be relevant in particular circumstances." (Legislative History at 425).

For example, the benefits of testing a chemical in the absence of hazard data is demonstrated by testing conducted under the cumene rule. The sponsors of the cumene testing conducted under the rule found effects of cumene that were important enough to submit to EPA under TSCA section 8(e), Notice to Administrator of Substantial Risks, prior to the time they were required to report the data under the test rule. Also, test sponsors indicated to EPA that they intended to notify workers and consumers about these results, reduce worker exposure to cumene, provide employee training and revise their material safety data sheets for cumene (Ref. 1).

EPA recognizes that it should not interpret the words "significant" and "substantial" in ways that would require it to make findings for every chemical in commerce, or the statute would have simply required testing for all chemicals. Nevertheless, TSCA section 4(a)(1)(B) is designed to support risk management activities under the other provisions of TSCA, including section 6. TSCA is different from most other environmental statutes in that it is intended to be preventative. To allow the continued widespread exposure to chemicals with unknown hazards would be contrary to the preventative goal of TSCA, which was expressed in the legislative history as follows:

> This vast volume of chemicals have, for the most part, been released into the environment with little or no knowledge of their long-term health or environmental effects. As a result, chemicals currently in commercial and household use are now being found to cause or contribute to health or environmental hazards unknown at the time commercial use of the chemical began.
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> [I]t is often many years after exposure to a harmful chemical before the effects of its harm become visible. By that time it may be too late to reverse those effects.
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> Because of the lack of testing by manufacturers and processors of chemicals to determine their health and environmental effects, the general population and the environment now serve as the laboratory for discovering adverse health and environmental effects. Aside from inequities in relying on human experience to indicate when a chemical is harmful, such a method is also a grossly inefficient way to identify problems.

(Legislative History at 411–413).

With greater than 60,000 chemical substances in commerce and a scarcity of knowledge on the vast majority, it is reasonable to interpret TSCA section 4(a)(1)(B) as authorizing EPA to require testing for every chemical that presents a scenario of environmental or human exposure which may need to be addressed on the basis of test data.

EPA is proposing quantitative criteria (numerical thresholds) and other factors that will generally be used to make those determinations while reserving the ability to consider other factors on a case-by-case basis. As a matter of course, EPA has reviewed past test rules promulgated under section 4(a)(1)(B) of TSCA, thresholds embraced in both EPA and non-EPA regulatory programs, and economic indices in developing these criteria. EPA believes that these proposed criteria and factors are both appropriate and reasonable for implementing the congressional mandate of requiring testing of chemicals under TSCA section 4(a)(1)(B).

EPA has implemented a policy designed to routinely seek data on new chemical substances which may present widespread human or environmental exposures that provides a starting point for the development of a policy for existing chemicals. Section 5(e) of TSCA provides EPA with the authority to regulate new substances pending development of health and environmental effects data based on either the potential risk presented by the substance (section 5(e)(1)(A)(ii)(I)) or the potential for substantial production volume and substantial or significant human exposure or substantial environmental release (section 5(e)(1)(A)(ii)(II)).

In initiating the section 5(e) policy, EPA developed criteria (guidelines) to define the terms "substantial" and "significant" in the section 5(e)(1)(A)(ii)(I) and 5(e)(1)(A)(ii)(II) findings. These guidelines are illustrated in Unit IV. A. of this notice. Because the production volumes of new substances are typically smaller until they have been in production for sometime and because of the greater uncertainty in accurately predicting the exposures which may result to humans and the environment from the manufacturing, processing, distribution in commerce, use, and/or disposal of these new substances, EPA has adopted threshold values for new substances which are lower than those which are being proposed in this notice for the testing of existing chemicals under TSCA section 4(a)(1)(B).

II. **Proposed Approach**

Substantial Production

ne first finding under TSCA section 4(a)(1)(B) is whether the chemical "is or will be produced in substantial quantities," referred to as "substantial production." EPA is proposing that a threshold value of 1 million pounds (lbs.), 454,000 kilograms (kgs.), be established as the substantial production threshold. EPA believes it is reasonable to interpret production in substantial quantities to mean large production, and that 1 million pounds is a large amount of production. The TSCA section 8(b) inventory of the chemical substances in commerce shows that only about 11 percent of the listed substances have production volumes over 1 million pounds, together accounting for over 95 percent of the total production volume of all substances produced in the United States (Ref. 2). EPA believes that TSCA section 4(a)(1)(B) gives EPA sufficient discretion to set the level of substantial production lower than 1 million pounds per year; however, it is well within reason to find that this small number of chemicals (i.e., the top 11 percent according to production volume), which account for the vast majority of all

oduction, clearly are chemicals with

stantial production as that term is

d in TSCA section 4(a)(1)(B).

owever, some may feel that a substantial production threshold value of 1 million pounds per year is too low a value; others may feel it is too high. Therefore, EPA is soliciting comments on adoption of a different threshold value and the supporting rationale for such choice.

Some manufacturers of chemicals for which TSCA section 4(a)(1)(B) findings would be made may claim that their individual production volumes of a particular chemical are confidential business information. EPA recognizes that whenever it makes a finding under TSCA section 4(a)(1)(B) based on the numerical threshold for substantial production (i.e., 1 million pounds per year), it would be publicly acknowledging that the chemical is or will be produced in the aggregate in quantities exceeding 1 million pounds per year. EPA does not believe that disclosing to the public the fact that a chemical is produced in at least 1 million pounds per year would be a disclosure of CBI. In making such a finding, EPA would be relying on the aggregate production volume of the

emical for all manufacturers. Thus,

would not be disclosing specific

rmation regarding any particular

duct. Moreover, a statement that a production volume is at least 1 million pounds, would not disclose sufficient information to be considered a disclosure of information which might be entitled to confidential treatment. In any event, TSCA section 14(a)(4) authorizes the disclosure of information which otherwise might be entitled to confidential treatment when relevant in any proceeding, including rulemaking, provided that disclosure is made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding. By disclosing only that a chemical is or will be produced in volumes of 1 million pounds per year or greater, EPA would preserve confidentiality to the extent practicable while still making findings under section 4(a)(1)(B).

B. Substantial Release

If the criterion for substantial production under section 4(a)(1)(B)(i)(I) is met, then at least one of the following three separate findings under section 4(a)(1)(B)(i)(II) would also have to be met to legally require testing: (1) There is or may be substantial release, (2) there is or may be substantial human exposure, or (3) there is or may be significant human exposure. Substantial release is discussed in this Unit II.B, while both human exposure components are discussed together in Unit II.C. of this notice.

EPA believes that the intent of Congress was that the phrase "enter the environment in substantial quantities" (referred to as "substantial release") captures chemicals for which there is or may be extensive release to the environment which, in itself, would be sufficient to require testing even in the absence of any information that the chemical may be hazardous to human health or the environment because such releases might be amenable to risk management. In other words, as with substantial production, release of substantial quantities means large release. EPA is proposing that, a value of 1 million pounds per year release or release of at least 10 percent of total production volume, whichever is lower, be established as the threshold. EPA believes that 1 million pounds of release to the environment each year is a sufficiently large amount of release where testing could be required even in the absence of any hazard information. The Toxics Release Inventory (TRI) (Ref. 3) established under section 313 of the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. 11023, shows that 37 percent of the listed chemicals have releases over 1 million pounds, accounting for over 99 percent of the total reported releases on the TRI by volume released. However, the TRI is comprised only of the releases of a select group of chemicals, and therefore may not be representative of the releases of all chemicals in commerce. EPA believes that because in actuality, only 11 percent of all chemicals are produced in quantities that exceed 1 million pounds, the percentage of those chemicals that are released in this quantity will be much smaller. Although EPA believes TSCA allows it the discretion to interpret substantial release at amounts lower than 1 million pounds per year, EPA believes it is reasonable to interpret the term "substantial release" to include this limited group of chemicals (i.e., less than 11 percent).

The alternative of at least 10 percent of production volume threshold is incorporated into this criterion to allow EPA some flexibility to require testing of chemicals that are produced in quantities equal to or greater than 1 million pounds per year, but that are released in amounts less than 1 million pounds per year. Although few chemicals with production volumes between 1 and 10 million pounds will have releases of greater than 10 percent of production volume, EPA believes it is reasonable to require testing of such chemicals because a release of 10 percent of production means that a sizable amount of what is being produced is escaping into the environment. Given the results of the testing, EPA may want to act to limit such releases. Again, by setting the level at 10 percent of production, EPA believes that this is a reasonable interpretation of EPA's authority under TSCA section 4(a)(1)(B).

However, some may feel that the 1 million pounds of release or 10 percent of production volume threshold may lead to inconsistent results. For instance, under these criteria a chemical with 1 million pounds of production and 100,000 pounds of release would met the criteria for substantial release, while a chemical with 2 million pounds of production and 100,000 pounds of release would not met the criteria for substantial release. Therefore, EPA solicits comments on the adoption of a fixed threshold, such as 100,000 pounds or 1 million pounds.

C. Substantial and Significant Human Exposure

The TSCA section 4(a)(1)(B) findings for human exposure have two bases: substantial or significant. Because a basic principle of statutory construction is that when Congress used two different words, it intended them to

have two different meanings, EPA believes that interpreting the two words to have different meanings is a reasonable interpretation of the statute. *United States v. Johnson*, 462 F.2d 463 (3rd Cir. 1972), cert. denied, 410 U.S 937 (1093). EPA has attempted to define these terms within the bounds established in TSCA and in its legislative history. Note that EPA can make a finding that there is or may be both significant human exposure and substantial human exposure if the number of people exposed exceeds the threshold set forth in the policy and the nature of the exposure is also significant as set forth in this policy. The following Table 1 compares the proposed criteria for "substantial" and "significant" exposure:

TABLE 1.—PROPOSED TSCA SECTION 4(A)(1)(B) HUMAN EXPOSURE CRITERIA

Category	Substantial	Significant
General population	100,000 people	< 100,000 people exposed more directly or on a routine or episodic basis
Consumers	10,000 people	< 10,000 people exposed more directly or on a routine or episodic basis
Workers	1,000 workers	< 1,000 workers exposed more directly or on a routine or episodic basis.

While there was little guidance provided by the statute itself or the legislative history, under TSCA EPA has traditionally interpreted the word "substantial" as a quantitative measure, referring in this case to widespread exposure-large numbers of people. EPA believes that it is reasonable to interpret the term "substantial human exposure" to mean widespread human exposure, or in other words, exposure to large numbers of people. This is reasonable because where large numbers of people are exposed to a chemical, EPA and others should have data indicating whether the chemical presents an unreasonable risk, to decide whether actions are necessary to protect the public against such unreasonable risk. EPA does not rely on levels of exposure in determining substantial exposure, because the risk presented by a level of exposure cannot be determined unless the toxicity of the chemical is known. Further, EPA can also require testing under TSCA section 4(a)(1)(B) to determine the level of exposure to a particular chemical.

EPA believes this is a reasonable interpretation of the word "substantial" because Congress made it clear that EPA should require testing under TSCA section 4(a)(1)(B) even in the absence of information that the chemical may be hazardous, if the other findings could be made. In risk assessment, it is necessary to take into account both the toxicity and the exposure to determine the risk. Under TSCA section 4(a)(1)(B), where there is or may be a substantial number of people exposed and toxicity is not characterized, EPA believes it is appropriate to obtain data on those chemicals for which EPA might consider further assessment. EPA believes that when there may be tens of thousands of people exposed to a chemical, thousands of consumers exposed to a chemical, or 1,000 workers exposed to a chemical, it is reasonable to require test data on that chemical. EPA believes that the different numerical thresholds for workers, consumers, and the general population are necessary to reflect the inherent differences in each probable exposure scenario (e.g., workers generally are exposed on a more routine or direct basis than consumers, and consumers are generally exposed on a more direct basis than the general public).

As a general matter, EPA has found that workers tend to be subject to routine or episodic exposure over a long period of time. Thus, exposure, to be considered substantial, does not have to be as widespread for workers as for consumers or the general population.

Similarly, TSCA and its legislative history provide little guidance about what constitutes significant human exposure. Under TSCA, EPA has generally interpreted the term "significant" as relating to the nature or importance of exposure. EPA therefore is proposing to interpret "significant" as referring to the nature of the exposure. EPA believes that if the nature of some exposure is sufficiently direct, large or prolonged, even if the number of people exposed is not "substantial", there is a need to develop data on the chemical because, on the basis of the data, EPA may take some risk management action to control the exposure.

By its interpretation of "significant human exposure," EPA does not adopt the approach suggested by CMA in the cumene litigation to require testing only if EPA demonstrates that people are exposed to levels that would be considered toxic if the chemical were found to be hazardous. EPA rejects this approach because it cannot know what level of exposure is hazardous until the chemical's toxicity has been fully tested. Currently, EPA and the scientific community do not have sufficient data about the universe of chemicals to set such an absolute cutoff level for requiring testing. Further, EPA rejects this approach because TSCA section 4 requires only that EPA find that there "is or may be significant or substantial human exposure" (emphasis added) to a chemical, not that EPA definitively prove exposure at a particular level.

A finding of significant exposure would generally be made where the numerical threshold for numbers of persons exposed for substantial exposure is not met, but the nature of the exposure is more direct than that which usually characterizes general population exposure, consumer exposure, or worker exposure. For example, if there is general population exposure to fewer than 100,000 people, but the nature of the exposure is quite direct, e.g., via drinking water, EPA may find that there is significant exposure for purposes of requiring testing under TSCA section 4. An example of significant consumer exposure might be where fewer than 10,000 consumers are exposed, but the consumers use the product near their food, or are likely to inhale it or dermally contact the substance.

EPA recognizes that the approach explained in this proposal integrates to some extent the concepts of "substantial" and "significant" in defining what constitutes "substantial human exposure" by distinguishing between the nature of the exposure to workers, consumers, and the general population. The Court in *CMA* recognized that there could be some overlap between substantial and significant human exposure: "*** it is not necessarily clear that 'significant' and 'substantial' as used in clause (II) must be understood in a way that prevents any overlap in their respective meanings or requires that any factor relevant to one be necessarily irrelevant to the other." *CMA* at 356, note 17. Finally, EPA believes its approach is a reasonable interpretation of its legal

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uthority because there must be bstantial production before EPA even siders whether there is or may be ubstantial release or significant or substantial human exposure. Thus the criteria listed above for release and exposure will not result in testing any chemicals other than those in the highest 11 percent of all chemicals produced.

D. Additional Factors

EPA would apply the generic numerical thresholds for most chemicals considered for action under TSCA section 4(a)(1)(B). In some cases, however, where the thresholds are not met, it may be more appropriate to use a case-by-case approach for making findings by applying other considerations. That is to say, EPA may consider "additional factors" for making findings for chemicals which do not meet the numerical thresholds proposed herein for evaluating existing chemicals under TSCA section 4(a)(1)(B). EPA's authority to use this flexible approach was recognized by the Court in its decision regarding the cumene test rule. The Court stated that EPA's definition need not be precise — it need not "function like a mathematical formula." Further, the Court stated EPA need not en adopt a definition applicable to all ses, but may proceed on a case-by- e interpretation, if it rationally explains its exercise of discretion. (*CMA* at 359.)

An example of an "additional factor" is bioaccumulation. Bioaccumulation refers to the tendency of certain chemicals to concentrate in animal tissue in increasing levels as it progresses up the food chain. The term refers to both uptake from water (bioconcentration) and uptake from ingested food and sediment residues (Ref. 4). Chemicals that bioaccumulate have been found in shellfish, birds, mammals, and human adipose tissue. As a general matter, EPA believes that the release to the environment of a chemical that bioaccumulates is of greater concern than the release of a substance that does not bioaccumulate. EPA believes that the persistence of a chemical in the environment, the subsequent storage of a chemical in animal tissue, and the likelihood for concentration of a chemical in the food chain are factors that could indicate that a chemical should be tested to determine if risk management measures are necessary even at release levels below those specified in the general iteria. Thus, release to the vironment of a chemical that accumulates may be considered to be stantial release even if the 1 million pound or 10 percent threshold for substantial release is not met.

Further, existence of a chemical in human adipose tissue may indicate widespread human exposure to the chemical, if the tissue survey represents a large population. Therefore, for example, exposure as demonstrated by existence of a chemical in the National Human Adipose Tissue Survey may be the basis for making a finding of substantial human exposure to the chemical.

Finally, in some cases, EPA may consider a category of chemicals for testing where it does not have information for each chemical within the category that shows that each chemical meets the thresholds established in this policy. In these cases, EPA believes it is reasonable to use the thresholds articulated in this notice for making findings on the entire category, rather than requiring EPA to show that each individual within the category meets the criteria set forth in this notice.

On the other hand, there may be some instances when a chemical meets the criteria proposed in this notice under TSCA section 4(a)(1)(B)(i), but EPA decides not to propose testing under TSCA section 4(a)(1)(B) because EPA finds that data are sufficient to reasonably determine or predict the effects of the manufacture, process, distribution, use and disposal of the chemical and/or that testing is not necessary.

III. Application of Proposed Criteria to the Final Test Rule for Cumene

EPA issued a final test rule under TSCA section 4(a)(1)(B), requiring manufacturers and processors of cumene to perform health effects testing. Based on the available data on cumene discussed in Unit II. of the preamble to the final rule (July 27, 1988, 53 FR 28195) (Ref.5) and Unit II. of the preamble to the proposed rule (November 6, 1985, 50 FR 46104), EPA found that cumene is produced in substantial quantities, that there is or may be substantial human exposure from its manufacture, processing, use, and disposal, and that it is released in substantial quantities to the environment based on estimates of release.

EPA found that cumene is produced in substantial quantities. EPA has found, and the Court in *CMA* upheld EPA's finding that U.S. production of cumene in 1984 was reported to be 3.35 billion pounds, and an additional 339 million pounds was imported. For the reasons discussed elsewhere in this notice, EPA finds that 1 million pounds of production per year is substantial production and therefore, cumene is produced in substantial quantities.

Based on release estimates, EPA found that cumene is released to the environment in substantial quantities. EPA has found, and the Court in *CMA* upheld EPA's finding that the fugitive emissions of cumene to the atmosphere from manufacturing, processing, and use activities are estimated to be 3 million pounds per year. For the reasons discussed elsewhere in this notice, 1 million pounds of release to the environment is substantial release, and therefore cumene may be released into the environment in substantial quantities.

EPA also found that there may be substantial human exposure to cumene. The industrial releases of cumene are concentrated in a few large metropolitan areas where the majority of cumene manufacturing and processing facilities are located. The Court in *CMA* found that the record adequately supported EPA's finding that approximately 13.5 million people living in the vicinity of cumene manufacturing and processing facilities may be exposed to this chemical.

When CMA briefed its case, it submitted a monitoring study not submitted as comments on the rule that relates to the presence of many chemicals in the Houston Ship Channel area; including cumene. CMA submitted the study in support of its argument that there was not substantial exposure to cumene. The Court in *CMA* said, "The extent to which this information may be material may significantly depend on the criteria articulated or developed by EPA on remand. We direct that EPA on remand afford CMA an opportunity to present such studies (and any others that EPA deems appropriate) unless they would not be material to any of EPA's criteria relied on for the testing" (*CMA* at 360–361).

EPA's preliminary review of the study indicates that the study presents the level of cumene found at certain times in the Houston Ship Channel area, rather than the number of people exposed. Because the criteria for finding that there is or may be substantial human exposure is based on the number of people which are or may be exposed, rather than the levels of exposure, the study does not relate to whether EPA could make a substantial human exposure finding. However, because the finding that there is substantial production and that there is or may be substantial release to the environment are legally sufficient to support the test rule and the testing of cumene has been completed, it is not necessary for EPA to

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give further consideration to the question of whether there is or may be substantial human exposure to cumene at this time.

Therefore, for the reasons set forth elsewhere in this notice proposing the minimum criteria for testing under TSCA section 4(a)(1)(B), and because cumene exceeded these thresholds, EPA finds that there is substantial production of cumene and there is or may be substantial release of cumene based on its manufacture, processing, use, and disposal.

IV. Alternatives to Proposed Criteria

A. *Substantial Production*

EPA considered other options for interpreting "substantial production": First, the 220,000 pound (100,000 kg.) substantial production threshold (Ref. 6) used by EPA under its TSCA section 5(e) authority; and second, a production volume threshold based on the uppermost quartile of chemicals produced. These two options would capture essentially the same chemicals. That is to say, chemicals with production volumes in or near the 220,000 pound range and above. EPA thinks that 220,000 pounds, while appropriate for new substances which inherently have smaller production volumes early in their commercial life, may be an unreasonably low production threshold for an existing chemical. For these reasons, EPA thinks that these options are less appropriate than the proposed criterion. EPA also solicits comment on whether a higher threshold should be used and the supporting rationale for using such a higher threshold.

B. *Substantial Release*

EPA considered other options for interpreting "substantial release": First, the 22,000 pound (10,000 kg.) substantial release (all environmental media) threshold used by EPA under its TSCA section 5(e) authority; second, a set threshold of 1 million pounds of release; and third, release greater than 10 percent of a chemical's production volume.

EPA believes that 22,000 pounds of release, while appropriate for new substances which inherently have smaller production and release volumes early in their commercial life, could include the release volumes of most existing commercial chemicals, and is therefore not indicative of the term "substantial release" as it relates to TSCA section 4(a)(1)(B).

Also, EPA believes that assigning a release threshold based solely on a fixed release volume of 1 million pounds is unreasonable and inappropriate for determining release into the environment of "substantial quantities" of chemicals. A fixed threshold of 1 million pounds would, in essence, exclude almost all chemicals with production volumes of between 1 and 10 million pounds from testing under TSCA section 4(a)(1)(B), based on release volume; rendering the 1 million pound "substantial production" threshold meaningless. This is because few chemicals with production volumes between 1 and 10 million pounds have releases which exceed 1 million pounds.

Finally, EPA rejected the percentage only approach because in the absence of data similar to TRI for all chemicals, it may be difficult for EPA to determine precisely what percentage of a chemical's production volume is released to the environment. Furthermore, even when releases are less than 10 percent of production volume, they may be large in quantity for extremely high production volume substances and therefore they merit testing. For these reasons, EPA believes that these options are less appropriate than the proposed criteria. EPA also solicits comment on whether a higher threshold should be used and the supporting rationale for using such a higher threshold.

C. *Substantial And Significant Human Exposure*

EPA considered other options for interpreting "substantial" and "significant" human exposure: First, define the terms "substantial" and "significant" solely on the basis of numbers of people exposed without regard to whether the persons are workers, consumers, or members of the general population, and base "significant" human exposure on the nature of exposure; or second, adopt the "substantial" and "significant" human exposure thresholds used by EPA under its TSCA section 5(e) authority (see Table 2.). EPA believes that the first option may not adequately address the inherent differences in magnitude and duration of exposures to workers, consumers, and the general population. Option 2 was rejected because new chemicals are more likely to have lower levels of exposure or less widespread exposure than existing chemicals and therefore the levels and numbers of persons exposed used by EPA in implementing TSCA section 5(e) may be more appropriate for new chemicals. For these reasons, EPA thinks these options are less appropriate than the proposed approach.

As discussed above, quantitative and qualitative guidelines have been established in interpreting each of the same statutory terms for the review of new substances pursuant to EPA's TSCA section 5(e) authority. In general, the guidelines used for evaluating new substances under section 5(e) have lower threshold values than those proposed herein for section 4(a)(1)(B). Therefore, EPA encourages public comment of the adoption of the section 5(e) guidelines for evaluating chemicals under section 4(a)(1)(B). If comments indicate to EPA that there is a sufficiently strong basis for adopting section 5(e) guidelines, or some other criteria, than the criteria proposed herein by EPA, EPA will consider adopting those criteria. The section 5(e) "substantial" and "significant" human exposure guidelines for all substances having annual production volumes of at least 220,000 pounds are as follows:

TABLE 2.—TSCA SECTION 5(e) HUMAN EXPOSURE GUIDELINES

Substantial and/or Significant Exposure Criteria	Description of Criteria
Worker:	
high number of workers exposed.	≧ 1,000 workers exposed (substantial)
acute worker exposure..	≧ 100 workers exposed by inhalation to ≧ 10 mg/day(substantial and significant)
chronic worker exposure:	
inhalation.....	≧ 100 workers exposed to 1–10 mg/day for ≧ 100 days/year (substantial and significant)
dermal.....	≧ 250 workers exposed to by routine dermal contact for ≧ 100 days/year (substantial and significant)
Consumer:	
consumer exposure	Presence of the substance in any product where (1) the physical state of the substance in the product; and (2) the manner of use would make exposures likely (significant)
General Population:	
ambient surface water exposure.	≧ 70 mg/year of exposure via surface water (significant)
ambient air exposure.....	≧ 70 mg/year of exposure via air (significant)
ambient groundwater.....	≧ 70 mg/year of exposure via groundwater (significant)

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TABLE 2.—TSCA SECTION 5(e) HUMAN EXPOSURE GUIDELINES—Continued

Substantial and/or Significant Exposure Criteria	Description of Criteria
aggregate ambient exposure through surface water, air, and groundwater (where leaching from landfill is expected).	≥ 22,000 lbs./year release to all environmental media (substantial)

EPA also solicits comment on whether a higher threshold should be used and the supporting rationale for using such a higher threshold.

V. Record

A. Supporting Documentation

EPA has established a record for this policy under TSCA section 4, docket number OPTS-47002J, which is available for inspection Monday through Friday, excluding legal holidays, in rm. NE-G004, 401 M St., SW., Washington, DC., 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. This record includes basic information considered by EPA in developing this policy. This record includes the following information:

(1) Interagency memoranda, comments, and proposals.

(2) Reports - published and unpublished data.

(3) Chemical Manufacturers Association v. EPA, 899 F.2d 344 (5th Cir. 1990).

B. References

(1) USEPA. Section 8(e) Notice, Public Docket Control No. 88-900000018, 8EHQ-0190-0846 FLWP, Office of Toxic Substances, USEPA (January 24, 1990).

(2) USEPA. Chemicals In Commerce Information Systems Search (CICIS). Office of Toxic Substances, USEPA (1977).

(3) USEPA. Toxic Release Inventory (TRI). Office of Toxic Substances, USEPA (1988).

(4) Casarett, L., and J. Doull. Toxicology: The Basic Science of Poisons. Macmillian Publishing Company, New York. (1986).

(5) USEPA. Cumene; Final Test Rule (OPTS-4207A; FRL 3420-2. Office of Toxic Substances, USEPA (July 25, 1988).

(6) USEPA. Implementation Proposal; "New Chemicals Exposure-Based Finding," letter from Charles L. Elkins to Geraldine V. Cox (Chemical Manufacturers Association). Office of Toxic Substances, USEPA (September 22, 1988).

Dated: July 5, 1991.

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